

FILING DATE

UNITED STATE PARTMENT OF COMMERCE Patent and Trailliark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 09/014,087 APPLICATION NUMBER ATTY, DOCKET NO.

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FIRST NAMED APPLICANT

01/27/98 CARLYLE 09/014,087

W 07001/065001 EXAMINER

QM31/0330

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AHTUNIT PAPER NUMBER 3738

DATE MAILED:

03/30/99

	COMMISSIONER OF PATENTS AND TRADEMARKS			
OFFICE ACTION SUMMARY				
	Responsive to communication(s) filed on			
	This action is FINAL.			
	Since this application is in condition for allowance except for formal matters, prosecution as to t accordance with the practice under <i>Ex parte Quayle</i> , 1935 D.C. 11; 453 O.G. 213.	the merits is clos	ed in	
whice	hortened statutory period for response to this action is set to expire <u>thirty days</u> mechanisms is longer, from the mailing date of this communication. Failure to respond within the period application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under 36(a).	l for response will	cause .	
Dis	position of Claims			
Ø	Claim(s) 1-20 is/are pending in the application			
	Of the above, claim(s)is/a	re withdrawn fron	consideration.	
	Claim(s)	-	e allowed.	
H	Claim(s)		e rejected. Objected to.	
网	Claim(s)is/are objected to. Claim(s)are subject to restriction or election requirement.			
	plication Papers			
R	See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.			٠.
6	The drawing(s) filed onis/are objected to by the The proposed drawing correction, filed onis [Examiner.		:
	The proposed drawing correction, filed onis [approved [disapproved.	• , .
	The specification is objected to by the Examiner.		•	•
	The oath or declaration is objected to by the Examiner.		*.*	•
Pric	ority under 35 U.S.C. § 119	•		
	Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).		•	
E	All Some* None of the CERTIFIED copies of the priority documents have been	,	٠	
	received.		÷	
	received in Application No. (Series Code/Serial Number)	<u>.</u>		
	received in this national stage application from the International Bureau (PCT Rule 17.2(a)).			•
	*Certified copies not received:		·. ·	
ч	Acknowledgment is made of a claim for domestic priority under 35 0.3.0. § 119(6).			
Att	achment(s)			
	Notice of Reference Cited, PTO-892			
	Information Disclosure Statement(s), PTO-1449, Paper No(s).			
	Interview Summary, PTO-413			
M	Notice of Draftperson's Patent Drawing Review, PTO-948			
$\overline{\Box}$	Notice of Informal Patent Application, PTO-152			
_	-SEE OFFICE ACTION ON THE FOLLOWING PAGES-			
PTCL	L 326 (Rev 9/96)	*	J.S. GPO: 1996-404-490	8/4051

Election/Restriction

Claims 12 and 13 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 5 filed April 27, 1999.

Applicant's election with traverse of Group I in Paper No. 5 is acknowledged. The traversal is on the ground(s) that there is no additional burden to search the article claims. This is not found persuasive because there is clearly an additional burden to search class 106 with Group II which is not required for the search of Group I.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

The drawings are considered to be informal because they fail to comply with 37 CFR 1.84(a)(1) which requires black and white drawings using India ink or its equivalent.

Photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(1) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the photographs or color drawings as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(i), three sets of drawings or photographs, as appropriate, and, if filed under the provisions of 37 CFR 1.84(a)(2), an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

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The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

The drawings are objected to because there is no detail discernable in the current photograph photocopies such that they do not aid in the examination of the application.

Correction is required.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 9-11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bayne et al (EP 0476983) alone.

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Bayne et al anticipates the claim language wherein the artificial vessel as claimed is the fixed umbilical vein which would be allogeneic and crosslinked or fixed prior to coating covalently or noncovalently with proteins and growth factors; see the whole document, especially page 8, lines 14-26.

Alternatively, one could take the position that the umbilical vein is not necessarily allogeneic as set forth above. However, the Examiner posits that the use of an allogeneic umbilical vein would have been considered at least obvious to one of ordinary skill because it would have lower antigenic reaction than one taken from a different species of animal.

With regard to claim 4 specifically, the linker molecule is the protein coating of Bayne et al which contains protein molecules which serve an attachment means or link to the underlying umbilical vein.

Claims 1, 2, 6, 7, 9-11, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tischer et al (US 5,194,596) in view of Orton (US 5,192,312). Tischer et al discloses a transplant which is soaked in VEGF prior to implantation, but fails to disclose the form of tissue used such as allogeneic or xenogeneic tissue as claimed. However, Orton teaches that it was known to use allogeneic and xenogeneic heart valve tissue of porcine origin in similar growth factor treated tissues; see the whole document. Hence, it is the Examiner's position that it would have been obvious to use a xenogeneic or porcine heart valve tissue as the transplant tissue vascular graft of Tischer because of the high availability and low cost of such tissue.

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Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tischer et al and

Orton as applied to claims 1, 2, 6, 7, 9-11, and 14-15 above, and further in view of Carpentier et

al (US 4,648,881). Both Tischer et al and Orton fail to disclose the use of bovine pericardial

tissue for the tissue as claimed. However, Carpentier et al teaches that bovine pericardial tissue

was known and used in the art to construct heart valves of reduced calcification; see the whole

document, especially column 2, lines 56-67. Hence, it is the Examiner's position that it would

have been obvious to use bovine pericardial tissue for the tissue of Tischer et al so that the

chances for calcification formation would be reduced over the tissues of Tischer et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's

disclosure.

Any inquiry concerning this communication or earlier communications from the examiner

should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner

normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor,

Mickey Yu, can be reached on (703) 308-2672. The fax phone number for this Technology

Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be

directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

Paul Prebilic

Primary Examiner

Paul Prelit

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